

## PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents  
United States Patent and Trademark  
Office  
Box PCT  
Washington, D.C.20231  
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 27 July 2000 (27.07.00)	
International application No. PCT/AU99/01108	Applicant's or agent's file reference 2/7570/PC-RK
International filing date (day/month/year) 13 December 1999 (13.12.99)	Priority date (day/month/year) 11 December 1998 (11.12.98)
Applicant FRAZER, Ian et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

24 May 2000 (24.05.00)

☐ in a notice effecting later election filed with the International Bureau on:2. The election ☒ was☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

F. Baechler

Telephone No.: (41-22) 338.83.38

REC'D 10 OCT 2000

WIPO

PCT

Applicant's or agent's file reference 2/7570/PC	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No. PCT/AU99/01108	International filing date (day/month/year) 13 December 1999	Priority Date (day/month/year) 11 December 1998
International Patent Classification (IPC) or national classification and IPC  Int. Cl. <sup>7</sup> A61K 39/12; A61P 31/20		
Applicant THE UNIVERSITY OF QUEENSLAND et al		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.																								
2.	<p>This REPORT consists of a total of 3 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheet(s).</p>																								
3.	<p>This report contains indications relating to the following items:</p> <table border="0"> <tr> <td>I</td> <td><input checked="" type="checkbox"/></td> <td>Basis of the report</td> </tr> <tr> <td>II</td> <td><input type="checkbox"/></td> <td>Priority</td> </tr> <tr> <td>III</td> <td><input type="checkbox"/></td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td>IV</td> <td><input type="checkbox"/></td> <td>Lack of unity of invention</td> </tr> <tr> <td>V</td> <td><input checked="" type="checkbox"/></td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td>VI</td> <td><input type="checkbox"/></td> <td>Certain documents cited</td> </tr> <tr> <td>VII</td> <td><input type="checkbox"/></td> <td>Certain defects in the international application</td> </tr> <tr> <td>VIII</td> <td><input type="checkbox"/></td> <td>Certain observations on the international application</td> </tr> </table>	I	<input checked="" type="checkbox"/>	Basis of the report	II	<input type="checkbox"/>	Priority	III	<input type="checkbox"/>	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	IV	<input type="checkbox"/>	Lack of unity of invention	V	<input checked="" type="checkbox"/>	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	VI	<input type="checkbox"/>	Certain documents cited	VII	<input type="checkbox"/>	Certain defects in the international application	VIII	<input type="checkbox"/>	Certain observations on the international application
I	<input checked="" type="checkbox"/>	Basis of the report																							
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VII	<input type="checkbox"/>	Certain defects in the international application																							
VIII	<input type="checkbox"/>	Certain observations on the international application																							

Date of submission of the demand 24 May 2000	Date of completion of the report 4 October 2000
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  BERNARD NUTT Telephone No. (02) 6283 2491

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☒ the international application as originally filed.
- ☐ the description,      pages , as originally filed,  
   pages , filed with the demand,  
   pages , received on      with the letter of
- ☐ the claims,      pages , as originally filed,  
   pages , as amended (together with any statement) under Article 19,  
   pages , filed with the demand,  
   pages , received on      with the letter of
- ☐ the drawings,      pages , as originally filed,  
   pages , filed with the demand,  
   pages , received on      with the letter of
- ☐ the sequence listing part of the description:  
   pages , as originally filed  
   pages , filed with the demand  
   pages , received on      with the letter of

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, was on the basis of the sequence listing:**

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description,      pages
- ☐ the claims,      Nos.
- ☐ the drawings,      sheets/fig.

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims 15-25	YES
	Claims 1-14, 26-31	NO
Inventive step (IS)	Claims 15-25	YES
	Claims 1-14, 26-31	NO
Industrial applicability (IA)	Claims 1-31	YES
	Claims -	NO

**2. Citations and explanations (Rule 70.7)**

## Citations:

D1: WO 98/28003 (MERCK &amp; CO., INC) 2 July 1998

D2: WO 98/10790 (MERCK &amp; CO., INC) 19 March 1998

D3: US 5716620 (LOWY D.R. et al) 10 February 1998

D4: US 5821087 (LOWE R. et al) 13 October 1998

D6: WO 96/30520 (MERCK &amp; CO., INC) 3 October 1996

D7: WO 98/44944 (MERCK &amp; CO., INC) 15 October 1998

D9: WO 98/15631 (FONDATION POUR LE PERFECTIONNEMENT ET LA RECHERCHE EN GYNECOLOGIE-OBSTETRIQUE) 16 April 1998

D10: WO 96/29413 (MERCK &amp; CO., INC) 26 September 1996

D11: WO 96/15247 (MERCK &amp; CO., INC) 23 May 1996

Claims 1-14 and 26-31 are not considered to be novel or to involve an inventive step. Citations D1,D2,D3,D5 and D9-D11 disclose methods of treating papillomavirus infection. The citations disclose the use of recombinant early and late viral proteins in therapeutic vaccines.

Claims 15-25 are considered to be novel and inventive as none of the cited documents predict the cross reactivity between HPV 11 and HPV 6.

The invention is industrially applicable in the treatment of papillomavirus infection.

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>2/7570/PC</b>	<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <b>FOR FURTHER ACTION</b> </div> <div style="width: 55%;"> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416). </div> </div>	
International application No. <b>PCT/AU99/01108</b>	International filing date ( <i>day/month/year</i> ) <b>13 December 1999</b>	Priority Date ( <i>day/month/year</i> ) <b>11 December 1998</b>
International Patent Classification (IPC) or national classification and IPC <b>Int. Cl. <sup>7</sup> A61K 39/12; A61P 31/20</b>		
Applicant <b>THE UNIVERSITY OF QUEENSLAND et al</b>		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.																								
2.	This REPORT consists of a total of <b>3</b> sheets, including this cover sheet. <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of      sheet(s).																								
3.	This report contains indications relating to the following items: <table style="width: 100%; margin-top: 10px;"> <tr> <td style="width: 5%;">I</td> <td style="width: 5%;"><input checked="" type="checkbox"/></td> <td>Basis of the report</td> </tr> <tr> <td>II</td> <td><input type="checkbox"/></td> <td>Priority</td> </tr> <tr> <td>III</td> <td><input type="checkbox"/></td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td>IV</td> <td><input type="checkbox"/></td> <td>Lack of unity of invention</td> </tr> <tr> <td>V</td> <td><input checked="" type="checkbox"/></td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td>VI</td> <td><input type="checkbox"/></td> <td>Certain documents cited</td> </tr> <tr> <td>VII</td> <td><input type="checkbox"/></td> <td>Certain defects in the international application</td> </tr> <tr> <td>VIII</td> <td><input type="checkbox"/></td> <td>Certain observations on the international application</td> </tr> </table>	I	<input checked="" type="checkbox"/>	Basis of the report	II	<input type="checkbox"/>	Priority	III	<input type="checkbox"/>	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	IV	<input type="checkbox"/>	Lack of unity of invention	V	<input checked="" type="checkbox"/>	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	VI	<input type="checkbox"/>	Certain documents cited	VII	<input type="checkbox"/>	Certain defects in the international application	VIII	<input type="checkbox"/>	Certain observations on the international application
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Date of submission of the demand <b>24 May 2000</b>	Date of completion of the report <b>4 October 2000</b>
Name and mailing address of the IPEA/AU <b>AUSTRALIAN PATENT OFFICE  PO BOX 200, WODEN ACT 2606, AUSTRALIA  E-mail address: pct@ipaustalia.gov.au  Facsimile No. (02) 6285 3929</b>	Authorized Officer  <b>BERNARD NUTT</b> Telephone No. (02) 6283 2491

**I. Basis of the report**

1. With regard to the elements of the international application:\*
- ☒ the international application as originally filed.
- ☐ the description,      pages      , as originally filed,  
   pages      , filed with the demand,  
   pages      , received on      with the letter of
- ☐ the claims,      pages      , as originally filed,  
   pages      , as amended (together with any statement) under Article 19,  
   pages      , filed with the demand,  
   pages      , received on      with the letter of
- ☐ the drawings,      pages      , as originally filed,  
   pages      , filed with the demand,  
   pages      , received on      with the letter of
- ☐ the sequence listing part of the description:  
   pages      , as originally filed  
   pages      , filed with the demand  
   pages      , received on      with the letter of
2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.  
These elements were available or furnished to this Authority in the following language which is:
- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
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3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, was on the basis of the sequence listing:
- ☐ contained in the international application in written form.
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- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
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4. ☐ The amendments have resulted in the cancellation of:
- ☐ the description,      pages
- ☐ the claims,      Nos.
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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

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\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims 15-25	YES
	Claims 1-14, 26-31	NO
Inventive step (IS)	Claims 15-25	YES
	Claims 1-14, 26-31	NO
Industrial applicability (IA)	Claims 1-31	YES
	Claims -	NO

**2. Citations and explanations (Rule 70.7)**

**Citations:**

D1: WO 98/28003 (MERCK & CO., INC) 2 July 1998

D2: WO 98/10790 (MERCK & CO., INC) 19 March 1998

D3: US 5716620 (LOWY D.R. et al) 10 February 1998

D4: US 5821087 (LOWE R. et al) 13 October 1998

D6: WO 96/30520 (MERCK & CO., INC) 3 October 1996

D7: WO 98/44944 (MERCK & CO., INC) 15 October 1998

D9: WO 98/15631 (FONDATION POUR LE PERFECTIONNEMENT ET LA RECHERCHE EN GYNECOLOGIE-OBSTETRIQUE) 16 April 1998

D10: WO 96/29413 (MERCK & CO., INC) 26 September 1996

D11: WO 96/15247 (MERCK & CO., INC) 23 May 1996

Claims 1-14 and 26-31 are not considered to be novel or to involve an inventive step. Citations D1, D2, D3, D5 and D9-D11 disclose methods of treating papillomavirus infection. The citations disclose the use of recombinant early and late viral proteins in therapeutic vaccines.

Claims 15-25 are considered to be novel and inventive as none of the cited documents predict the cross reactivity between HPV 11 and HPV 6.

The invention is industrially applicable in the treatment of papillomavirus infection.

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 2/7570/pc-rtk	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/AU 99/01108	International filing date (day/month/year) 13 December 1999	(Earliest) Priority Date (day/month/year) 11 December 1998
Applicant 1. THE UNIVERSITY OF QUEENSLAND ET AL		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

## 1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☐ Unity of invention is lacking (See Box II).

4. With regard to the title, ☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract, ☒ the text is approved as submitted by the applicant

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure

☐ because this figure better characterizes the invention

☒ None of the figures



**A. CLASSIFICATION OF SUBJECT MATTER**Int Cl<sup>7</sup>: A61K 39/12; A61P 31/20

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**Minimum documentation searched (classification system followed by classification symbols)  
IPC A61K AND KEYWORDS BELOWDocumentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
AU: IPC AS ABOVEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
Derwent, Chemical Abstracts. Keywords: papillomavirus, L1, L2, virus like protein, capsid protein, hpv11, hpv6, treatment, vaccine.**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98/28003 A (MERCK & CO., INC) 2 July 1998 (See whole document)	1-14, 26-31
X	WO 98/10790 A (MERCK & CO., INC) 19 March 1998 (See whole document)	1-14, 26-31
X	US 5716620 A (LOWY D.R. <u>et al</u> ) 10 February 1998 (See whole document)	1-14, 26-31

☒ Further documents are listed in the  
continuation of Box C☒ See patent family annex

* Special categories of cited documents:	
"A" Document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search  
02 February 2000Date of mailing of the international search report  
21 FEB 2000Name and mailing address of the ISA/AU  
AUSTRALIAN PATENT OFFICE  
PO BOX 200  
WODEN ACT 2606 AUSTRALIA  
E-mail address: pct@ipaustalia.gov.au  
Facsimile No.: (02) 6285 3929Authorized officer  
  
**BERNARD NUTT**  
Telephone No.: (02) 6283 2491

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5821087 A (LOWE R. <u>et al</u> ) 13 October 1998 (See whole document)	1-25
P,X	WO 99/18220 A (LOYOLA UNIVERSITY OF CHICAGO) 15 April 1999 (See whole document)	1-14, 26-31
X	WO 96/30520 A (MERCK & CO., INC) 3 October 1996 (See whole document)	1-25
X	WO 98/44944 A (MERCK & CO., INC) 15 October 1998 (See whole document)	1-25
P, X	WO 99/09177 A (DEUTSCHES KREBSFORSCHUNGSZENTRUM STIFTUNG DES ÖFFENTLICHEN RECHTS) 25 February 1999 (See whole document)	1-14, 26-31
X	WO 98/15631 A ( FOUNDATION POUR LE PERFECTIONNEMENT ET LA RECHERCHE EN GYNECOLOGIE-OBSTETRIQUE) 16 April 1998 (See whole document)	1-14, 26-31
X	WO 96/29413 A (MERCK & CO., INC) 26 September 1996 (See whole document)	1-14, 26-31
X	WO 96/15247 A (MERCK & CO., INC) 23 May 1996 (See whole document)	1-14, 26-31

# INTERNATIONAL SEARCH REPORT

## Information on patent family members

International application No.  
PCT/AU 99/01108

- This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
WO	9828003	AU	56087/98	EP	957936		
WO	9810790	AU	42582/97				
US	5716620	EP	662132	JP	8504087	WO	9405792
		AU	38284/95				
US	5821087	AU	55277/96	CA	2216827	CN	1185810
		EP	817852	WO	9630520	JP	11503313
WO	9918220	AU	96846/98				
WO	9630520	CA	2216827	CN	1185810	EP	817852
		JP	11503313	US	5821087		
WO	9844944	AU	69533/98	EP	973546		
WO	9909177	DE	19735118				
WO	9815631	EP	932683	AU	45668/97		
WO	9629413	AU	53141/96	CA	2215834	CN	1185176
		EP	817851	JP	11502704	US	5840306
WO	9615247	AU	43658/96	CN	1173203	EP	789767
		JP	11500002				
END OF ANNEX							